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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,124	06/24/2008	Kevin Clairmont	5189	1358

35969 7590 10/08/2009

Barbara A. Shimci
Director, Patents & Licensing
Bayer HealthCare LLC - Pharmaceuticals
555 White Plains Road, Third Floor
Tarrytown, NY 10591

EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
10/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,124	CLAIRMONT ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 12-16, 50, 51 and 53, drawn to a polypeptide selected from the group consisting of SEQ ID NOs: 1-148.

Group II, claim(s) 3-5 and **11 (in part)**, drawn to an antibody that specifically binds the polypeptide of Group I.

Group III, claim(s) 6-8 and **11 (in part)**, drawn to antibody that binds specifically to polyethylene glycol.

Group IV, claim(s) **9 and 10 (both in part)**, drawn to a method for detecting the polypeptide of Group I in a sample, comprising contacting the sample with an antibody of Group II.

Group V, claim(s) **9 and 10 (both in part)**, drawn to a method for detecting the polypeptide of Group I in a sample, comprising contacting the sample with an antibody of Group III.

Group VI, claim(s) 17-36 and **49 (in part)**, drawn to a method of treating diabetes, Syndrome X or diabetes related disorders, comprising administration of a polypeptide or pharmaceutical composition of Group I.

Group VII, claim(s) 37, drawn to a method of treating respiratory disease, comprising administration of a polypeptide or pharmaceutical composition of Group I.

Group VIII, claim(s) 38, drawn to a method of treating obesity, comprising administration of a polypeptide or pharmaceutical composition of Group I.

Group IX, claim(s) 39 and 40, drawn to a method of treating cardiovascular disease, comprising administration of a polypeptide or pharmaceutical composition of Group I.

Group X, claim(s) 41 and **49 (in part)**, drawn to a method of treating lipid and carbohydrate metabolism disorders, comprising administration of a polypeptide or pharmaceutical composition of Group I.

Group XI, claim(s) 42, drawn to a method of treating sleep disorders, comprising administration of a polypeptide or pharmaceutical composition of Group I.

Group XII, claim(s) 43, drawn to a method of treating male reproductive disorders, comprising administration of a polypeptide or pharmaceutical composition of Group I.

Group XIII, claim(s) 44 and **49 (in part)**, drawn to a method of treating growth disorders or disorders of energy homeostasis, comprising administration of a polypeptide or pharmaceutical composition of Group I.

Group XIV, claim(s) 45 and 46, drawn to a method of treating immune diseases, comprising administration of a polypeptide or pharmaceutical composition of Group I.

Group XV, claim(s) 47 and 48, drawn to a method of treating acute and chronic inflammatory diseases, comprising administration of a polypeptide or pharmaceutical composition of Group I.

Group XVI, claim(s) 52, drawn to use of a polypeptide of Group I for manufacturing a medicament for the treatment and/or prophylaxis of diabetes or a diabetes-related condition.

It is noted that several claims encompass subject matter that spans several inventions (set forth in bold above). If applicants elect any of the groups that encompass these claims, said claims will only be examined to the extent that they read on the elected invention.

The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XVI is that they all relate to a polypeptide of SEQ ID NOs: 1-148, and functionally equivalent fragments, derivatives, and variants thereof and a method for detecting said polypeptide, comprising the use of an antibody to the polypeptide. However, Froland et al. (WO 2004/006839, published 22 January 2004, Cite No. F4 on IDS dated 14 July 2006) teaches a polypeptide that is 100% identical to SEQ ID NO: 1 (see sequence alignment, below) and methods to detect this polypeptide comprising detecting an antibody bound to the polypeptide. Thus, the technical feature linking the inventions of Groups I-XVI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

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SEQ ID NO: 1
ADI23990
ID   ADI23990 standard; peptide; 31 AA.
XX
AC   ADI23990;
XX
DT   22-APR-2004  (first entry)
XX
DE   VPAC2 receptor agonist peptide SEQ ID NO:1.
XX
KW   VPAC2; pituitary adenylate cyclase activating peptide; PACAP;
KW   antidiabetic; anorectic; cardiant; immunomodulator; antiinflammatory;
KW   respiratory; analgesic; antianginal; antibacterial; gene therapy;
KW   vaccine; diabetes; Syndrome X; respiratory disease; obesity;
KW   sleep disorder; growth disorder; energy homeostasis disorder;
KW   immune disease; cardiovascular disease; inflammatory disease;
KW   septic shock.
XX
OS   Homo sapiens.
XX
PN   WO2004006839-A2.
XX
PD   22-JAN-2004.
XX
PF   11-JUL-2003; 2003WO-US021761.
XX
PR   12-JUL-2002; 2002US-0395738P.
XX
PA   (FARB ) BAYER PHARM CORP.
XX
PI   Froland WA,  Kelner DN,  Dumas ML,  Pan C,  Whelan J,  Wang YJ;
PI   Wang W;
XX
DR   WPI; 2004-122754/12.
XX
PT   New polypeptide, useful for preparing a composition for treating
PT   diabetes, Syndrome X, diabetes-related disorders, respiratory disease,
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PT   obesity, disorders of lipid and carbohydrate metabolism, sleep disorders
PT   or septic shock.
XX
PS   Claim 1; SEQ ID NO 1; 128pp; English.
XX
CC   The invention relates to a novel polypeptide comprising a sequence having
CC   30-32 amino acids or its functionally equivalent fragments, derivatives
CC   or variants. A polypeptide of the invention has antidiabetic, anorectic,
CC   cardiant, immunomodulator, antiinflammatory, respiratory, analgesic,
CC   antianginal, and antibacterial activity, and may have a use in gene
CC   therapy and as a vaccine. The polypeptide is useful for preparing a
CC   composition for treating diabetes, Syndrome X, diabetes-related
CC   disorders, respiratory disease, obesity, disorders of lipid and
CC   carbohydrate metabolism, sleep disorders, growth disorders or disorders
CC   of energy homeostasis, immune diseases, cardiovascular disease, acute and
CC   chronic inflammatory diseases, septic shock or preventing secondary
CC   causes of diabetes. The present sequence represents a peptide of the
CC   invention.
XX
SQ   Sequence 31 AA;

  Query Match             100.0%;  Score 157;  DB 1;  Length 31;
  Best Local Similarity   100.0%;
  Matches   31;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 HSDAVFTDQYTRLRKQVAAKKYLQSIKQKRY 31
              |||||||||||||||||||||||||||||||
Db          1 HSDAVFTDQYTRLRKQVAAKKYLQSIKQKRY 31
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Requirement For Further Restriction Within Groups I-XVI

Applicants are required, in reply to this action, **to elect a single sequence, i.e. a single polypeptide sequence selected from the group consisting of SEQ ID NOs: 1-148** (see PCT Rule 13.3, Determination of Unity of Invention Not Affected by Manner of Claiming, which states that the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim).

Applicants are advised that the reply to this requirement to be complete must include (i) **election of invention** to be examined even though the requirement be

traversed (37 CFR 1.143) and (ii) **identification of the claims encompassing the elected invention**.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicants traverse on the ground that the inventions or species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 - 5:30 M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached at (571)272-09110911. The fax phone

number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G.E./

Gregory S. Emch
Patent Examiner
Art Unit 1649
07 October 2009

/Daniel E. Kolker/
Primary Examiner, Art Unit 1649
October 7, 2009